EXHIBIT 70

DEFENDANT'S EXHIBIT 70

Form Approved: OMB No. 0910-0001. Expiration Date: November 30, 2001
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*
NJ District (NWJ-DO)
Waterview Corporate Center
10 Waterview Blvd.
Parsippany, NJ 07054

TYPE OF REPORT ☒ Initial ☐ Follow-Up ☐ Final

In accordance with Section 314.81 (b)(i) and (ii) of the New Drug and Antibiotic Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. NDA/ANDA - ANTIBIOTIC FORM 5/6 NO.
40-282

2. GENERIC NAME OF DRUG PRODUCT
Digoxin Tablets 0.25 mg

3. TRADE NAME *(if any)* OF DRUG PRODUCT
Digitek Tablets 0.25 mg

4. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)
Tablets 0.25 mg

5. LOT NUMBER(S)
3611A

6. EXPIRATION DATE(S) OF DRUG PRODUCTS
Dec 2004

7. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER
Initial 5/17/04 Samples received 7/6/04.

8. SOURCE(S) OF REPORT
Pharmacist

9. PROBLEM(S) ASSOCIATED WITH DRUG PRODUCT
Thick Tablet

10. PROBABLE CAUSE(S) OF PRODUCT PROBLEM(S)
Initial Set up of the tablet press

11. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)
Clearance checks initiated and documented by production and Quality Assuranc

12. REMARKS

NOTE: FOR ITEMS 9, 10, 11, AND 12, SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT

NAME AND MAILING ADDRESS *(Include ZIP Code)*
Amide Pharmaceutical, Inc.
101 East MAin Street
Little Falls, NJ 07424

NAME AND TITLE OF AUTHORIZED REPRESENTATIVE
Jasmine Shah, Dir. Reg Affairs

TELEPHONE *(Include Area Code)*
(973)890-1440

SIGNATURE OF AUTHORIZED REPRESENTATIVE
[signature]

DATE SUBMITTED
7/13/04

FORM FDA 3331 (12/98) PREVIOUS EDITION IS OBSOLETE

Created by Electronic Document Services/USDHHS (301) 443-2454 EF

Form Approved: OMB No. 0910-0001. Expiration Date: November 30, 2001
See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

NDA-FIELD ALERT REPORT

TO: *(NAME AND ADDRESS OF DISTRICT)*
NJ District (NWJ-DO)
Waterview Corporate Center
10 Waterview Blvd.
Parsipanny, NJ 07054

TYPE OF REPORT ☐ Initial ☐ Follow-Up ☒ Final

In accordance with Section 314.81 (b)(i) and (ii) of the New Drug and Antibiotic Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:

1. NDA/ANDA - ANTIBIOTIC FORM 5/6 NO.
40-282

2. GENERIC NAME OF DRUG PRODUCT
Digoxin Tablets 0.25 mg

3. TRADE NAME *(if any)* OF DRUG PRODUCT
Digitek Tablets 0.25 mg

4. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S)
Tablets 0.25 mg

5. LOT NUMBER(S)
3611A

6. EXPIRATION DATE(S) OF DRUG PRODUCTS
Dec 2004

7. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER
Initial 5/17/04 Samples received 7/6/04.

8. SOURCE(S) OF REPORT
Pharmacist

9. PROBLEM(S) ASSOCIATED WITH DRUG PRODUCT
Thick Tablet

10. PROBABLE CAUSE(S) OF PRODUCT PROBLEM(S)
Initial Set up of the tablet press

11. CORRECTIVE ACTION(S) TAKEN *(if any)* TO PREVENT RECURRENCE OF PROBLEM(S)
Clearance checks initiated and documented by production and Quality Assuranc

12. REMARKS

NOTE: FOR ITEMS 9, 10, 11, AND 12, SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT

NAME AND MAILING ADDRESS *(Include ZIP Code)*
Amide Pharmaceutical, Inc.
101 East MAin Street
Little Falls, NJ 07424

NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	TELEPHONE *(Include Area Code)*
Jasmine Shah, Dir. Reg Affairs	(973)890-1440
SIGNATURE OF AUTHORIZED REPRESENTATIVE	DATE SUBMITTED
	8/16/04

FORM FDA 3331 (12/98) PREVIOUS EDITION IS OBSOLETE Created by Electronic Document Services/USDHHS: (301) 443-2454 EF

Amide Pharmaceutical, Inc.
101 E. Main Street, Little Falls, NJ 07424 • Ph:(973) 890-1440 • Fax:(973) 890-7980

June 8, 2004

Amin Nanji
Rite Aid Pharmacy #5238
220 36th street
Bellington, WA 98222

RE: Digoxin Tablets 0.25
Amide Complaint # C04-016
Mylan Complaint # 2004S1001417

Dear Mr. Nanji:

In reference to your inquiry regarding thick Digoxin Tablets, Review of our production and manufacturing batch records do not indicate any problem during the manufacture of this batch. Please provide the sample for our evaluation so we may investigate the cause.

Thank you for bringing this to our attention and we apologize for this inconvenience. If you need any further information please contact us at (973)890-1440.

Sincerely,
AMIDE PHARMACEUTICAL, INC.

Jasmine Shah, MS, R.Ph.
Director of Regulatory Affairs

Amide Pharmaceutical, Inc.
101 E. Main Street, Little Falls, NJ 07424 • Ph:(973) 890-1440 • Fax:(973) 890-7980

July 13, 2004

Amin Nanji
Rite Aid Pharmacy #5238
220 36th street
Bellington, WA 98222

RE: Digoxin Tablets 0.25
Amide Complaint # C04-016
Mylan Complaint # 2004S1001417

Dear Mr. Nanji:

In reference to your inquiry regarding thick Digoxin Tablets , Amide has completed its review of the complaint and following is our conclusion.

Review of the returned sample indicates that the tablets was thicker than normal. Amide conducted an investigation and concluded that the thick tablet may have been produced at the setup of the compression machine. Normal procedure is to reject all tablets manufactured at the set up stage and take Quality Assurance Approval. It may have been possible that a tablet may have been left in the tablet vibrator during the initial setup and may have passed undetected. This is an isolated incident and Amide has not received any other complaints regarding this. Amide has revised procedures to check the machines prior to start of compression.

Thank you for bringing this to our attention and we apologize for this inconvenience. If you need any further information please contact us at (973)890-1440.

Sincerely,
AMIDE PHARMACEUTICAL, INC.

Jasmine Shah, MS, R.Ph.
Director of Regulatory Affairs

AMIDE PHARMACEUTICAL, INC.

CUSTOMER COMPLAINT REPORT FORM

DATE RECEIVED 5/17/04 COMPLAINT NO. C04-016

PRODUCT Digoxin Tablet.

SIZE _____ LOT NO. 3611A1 EXP. DATE 11/05

COMPLAINANT Amin Nanji

ADDRESS Rite Aid Pharmacy # 5238
220 36Th Street.
Bellingham, WA 98222, USA

PHONE NO. 360-734-8254

NATURE OF COMPLAINT

One tablet with three times the thickness.

DOSAGE FORM _____ COMPLAINT CATEGORY _____

SAMPLE EVALUATION

DATE SAMPLE RECEIVED 7/6/04 RECEIVED VIA mail

PHYSICAL EVALUATION

Tablet is thicker than normal.

EVALUATED BY JS. DATE 7/7/04

AMIDE PHARMACEUTICAL, INC.

CUSTOMER COMPLAINT REPORT FORM

PRODUCT Digoxin Tablet COMPLAINT NO 004-08

REGULATORY AFFAIRS EVALUATION

Amide perform an investigation and the tablet may have been produced at the initial set up of machine. This is an isolated incident and may not be possible in normal production

EVALUATED BY JS. DATE 7/13/04.

LABORATORY EVALUATION

none

EVALUATED BY _____ DATE _____

CONCLUSIONS AND FOLLOW UP

COMPLAINT VALID (Y/N) Yes REPORT REQUIRED Yes.

COMMENTS

Submit Field Alert Report to FDA and also a copy of the investigation to FDA

FOLLOW UP ACTION TAKEN

none

REPORT ISSUED BY JS. DATE 7/13/04

May-17-04 07:20am From-MYLAN R AND D 3042856409 T-651 P.01/03 F-315

MYLAN

facsimile

TRANSMISSION

to: Jasmine Shah c/o Amide

fax no: 973-890-7980

re: Digitek

date: May ~~14~~ 17, 2004

from the desk of...
Ron Selders, R.Ph., MBA
Director, Product Surveillance
MYLAN Pharmaceuticals Inc.
3711 Collins Ferry Road
Morgantown, WV 26505
TEL: 304-599-2595
FAX: 304-285-6446

*You should receive **2 Page(s)** including this cover sheet. If you do not receive all the pages, please contact the number listed above.*

Quality complaint (2004S1001417) received for the Amide-manufactured, Bertek-marketed Digitek tablets.

If you have any further questions, please contact me at 1(800)826-9526, Ext: 6694.

Thanks
Ron Selders, R.Ph., MBA
Director, Product Surveillance

MYLAN PHARMACEUTICALS INC

P.O. Box 4310 Morgantown, West Virginia 26504-4310 U.S.A (304)599-2595

TELEPHONE LOG

Log Type: QUALITY **Complaint #:** 2004S1001417

Date:	14-MAY-04 **Time:** 04:22pm
Call taken by:	MWBACZKO
Person calling:	Mr. Amin Nanji, RPh
Address:	Rite Aid Pharmacy # 5238 220 36th Street Bellingham, WA 98225, USA
Phone number:	(360)734-8254 **Fax number:**
Product/strength:	1. DIGITEK (DIGOXIN) TABLETS, 0.25MG **Lot #:** 3611A1 **Exp Date:** 11/05
Product I.D.:	1. YES
Classification:	Thick tablet
Date of event:	N/A
Patient ID/Initials:	N/A
Age: N/A	**Sex:** N/A **Weight:** N/A
Relevant tests:	N/A
Medical history:	N/A
Dose, frequency, route used:	N/A
Indication: N/A	
Therapy dates:	N/A
Concomitant medical products/dates:	N/A
Event abated after dose stopped:	N/A
Event reappeared after reintroduction:	N/A

Conversation:

The pharmacist called regarding the Amide-manufactured, ~~Mylan~~ Bertek BB-marketed Digitek (digoxin) tablets, 0.25mg. The pharmacist reportedly found one tablet in the bottle that was three times the thickness of the standard tablet. The tablet contained the appropriate markings. The control number is documented above. Product is available for return. The pharmacist did not locate any additional tablets manufactured the same way. Product replacement was not requested.

*Forward to Amide

Reviewed By: Beverly A. Wright Date: 5/14/04

Note: All telephone logs (product identification, complaints, product information) must be forwarded to the attention of Ron Selders, R.Ph., MBA. Please deliver or fax any potential Quality complaints or Adverse Medical Events to (304) 285-6409.